

REMARKS

A. BACKGROUND

The present Amendment is in response to the Office Action mailed June 18, 2009. Claims 1-22 were pending, claims 4 and 11 were previously withdrawn, and claims 1-3, 5-10, and 12-22 were rejected in view of cited art.¹ Claims 17 and 20 are amended. Claims 1-22 are now pending in view of the above amendments.²

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

B. PRIOR ART REJECTIONS

I. REJECTION UNDER 35 U.S.C. § 103

The Office Action rejected claims 1-3, 5, 7-10, and 14-22 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,674,231 (*Green*) in view of U.S. Patent No. 6,447,540 (*Fontaine*). Claims 12-13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Green* in view of *Fontaine* as applied to claim 1, and further in view of U.S. Patent No. 5,593,412 (*Martinez*). Claim 6 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Green* in view of *Fontaine* as applied to claim 1, and further in view of U.S. Patent No. 5,868,755 (*Kanner*). Applicant respectfully traverses.

¹ Although the prior art status of the cited art is not being challenged at this time, Applicant reserves the right to challenge the prior art status of the cited art at any appropriate time, should the need arise. Accordingly, any arguments and amendments made herein should not be construed as acquiescing to any prior art status of the cited art.

² Support for the claim amendments and/or new claim(s) can be found throughout the specification and/or drawings as originally filed.

As amended herein, independent claim 1 recites, in part, "a skin overlying at least a portion of the outer surface between the carrier assembly and a distal end of the elongate member" and "advancing the carrier assembly towards the distal end of the elongate member, the carrier assembly causing the skin to separate from the outer surface of the elongate member from a proximal end of the skin toward a distal end of the skin as the carrier assembly is advanced towards the distal end"; independent claim 17 recites, in part, "a sleeve member having a proximal end disposed proximate the carrier assembly and a distal end disposed proximate the distal end of the elongate member" and "advancing the carrier assembly towards the distal end of the elongate member, the advancement of the carrier assembly causing the sleeve member to be disrupted from the proximal end of the sleeve member toward the distal end of the sleeve member to permit such advancement"; and independent claim 20 recites, in part, "a sleeve member having a proximal end disposed proximate the carrier assembly and a distal end disposed proximate a distal end of the elongate member" and "advancing the carrier assembly towards the distal end of the elongate member, the advancement of the carrier assembly causing the sleeve member to be expanded from the proximal end of the sleeve member toward the distal end of the sleeve member to permit such advancement." By contrast, neither *Green* nor *Fontaine* discloses, teaches, or suggests a method for delivering a closure element to seal an opening through tissue that incorporates each and every element as is presently claimed in independent claims 1, 17, and 20.

The Office Action asserts that "*Green* discloses . . . the closure element being carried by a carrier assembly 42 slidable on an outer surface of an elongate member 30 . . . the method comprising . . . advancing the carrier assembly towards the distal end of the elongate member, and deploying the closure element from the carrier assembly." (Office Action, 2-3.) Applicant respectfully disagrees. *Green* discloses "a surgical clip 22 . . . releasably supported on a distal end portion of elongated body 20." (Col. 5, ll. 30-32.) The surgical clip 22 is supported by a "clip support fixture 34," (Col. 5, ll. 50-51), not the pusher tube 42. *Green* further teaches that the clip support fixture 34 is "mounted in axial bore 30a adjacent the distal end of support shaft 30." (*Id.*) Applicant has found no portion of *Green* that teaches the surgical clip 22 being carried by the pusher tube 42 or that teaches the clip support fixture 34 being slidable with respect to the support shaft 30. In fact, modifying the clip support fixture 34 to be slidable with respect to the support shaft 30 would make the clip support fixture 34 unsatisfactory for its intended purpose since fixing the clip support fixture 34 relative to the support shaft 30 is

necessary to allow the pusher tuber 42 "to translate with respect thereto . . . to drive the surgical clip 22 distally." (Col. 5, l. 66-col. 6, l.1.) Accordingly, Applicant respectfully submits that the surgical clip 22 being supported by the clip support fixture 34 that is mounted to the support shaft 30 is not the same as "the closure element being carried by a carrier assembly slidable on the outer surface of an elongate member," as recited, in part, by independent claims 1, 17, and 20.

The Office Action correctly identifies that *Green* does not teach "a skin, or sleeve member, overlying at least a portion of the outer surface between the carrier assembly and a distal end of the elongate member and the carrier assembly causing the skin to separate from the outer surface of the elongate member." (Office Action, 3.) The Office Action also asserts that "*Fontaine* teaches a skin or sleeve 16 . . . overlying at least a portion of an outer surface between a carrier assembly 20 and a distal end of an elongate member 12 and the carrier assembly may cause the skin to separate or split from the outer surface." (*Id.*) However, Applicant respectfully disagrees that *Fontaine* teaches or suggests "advancing the carrier assembly towards the distal end of the elongate member, the carrier assembly causing the skin to separate from the outer surface of the elongate member from a proximal end of the skin toward a distal end of the skin" as recited, in part, by independent claim 1, "advancing the carrier assembly towards the distal end of the elongate member, the advancement of the carrier assembly causing the sleeve member to be disrupted from the proximal end of the sleeve member toward the distal end of the sleeve member" as recited, in part, by independent claim 17, or "advancing the carrier assembly towards the distal end of the elongate member, the advancement of the carrier assembly causing the sleeve member to be expanded from the proximal end of the sleeve member toward the distal end of the sleeve member," as recited, in part, by independent claim 20.

Rather, in direct contrast, *Fontaine* teaches a "sleeve 16 ha[ving] a portion 18 extending fully over and containing the stent 14" positioned on the distal end of the catheter 12. (Col. 6, ll. 26-28.) The sleeve 16 can be "substantially the same length as the catheter 12 and include[] a proximal end 38 fixed to the catheter 12" or "can be much shorter in length than the catheter 12, and can include a proximal end 40 fixed to the catheter." (Col. 7, ll. 4-11 (emphasis added).) As shown in Figures 7 and 10, the proximal end 38 and proximal end 40 remain fixed to the catheter 12 after the sleeve has been split. Furthermore, the sleeve portion 18 is split by inflation of "an inflatable, nondistending balloon 22" disposed on the distal end of the catheter 12, (Abstract), or by "[l]ongitudinal movement of the bulbous catheter end 24," (Abstract), which is initially

disposed distal of the sleeve 16 with "the stent 14 and the sleeve portion 18 [being] positioned proximally of the bulbous end 24," (col. 9, ll. 31-32). Applicant respectfully submits that splitting the distal sleeve portion 18 using an inflatable balloon or by proximal longitudinal movement of the bulbous catheter end 24 beginning at the distal end of the sleeve portion 18, as taught by *Fontaine*, is not the same as "advancing the carrier assembly towards the distal end of the elongate member, the carrier assembly causing the skin to separate from the outer surface of the elongate member from a proximal end of the skin toward a distal end of the skin," as recited, in part, by independent claim 1, "advancing the carrier assembly towards the distal end of the elongate member, the advancement of the carrier assembly causing the sleeve member to be disrupted from the proximal end of the sleeve member toward the distal end of the sleeve member" as recited, in part, by independent claim 17, or "advancing the carrier assembly towards the distal end of the elongate member, the advancement of the carrier assembly causing the sleeve member to be expanded from the proximal end of the sleeve member toward the distal end of the sleeve member," as recited, in part, by independent claim 20.

Even if the Office Action had cited to Figures 11A and 11B, which show a "means 54 for splitting the entire sleeve 16 between its proximal end 38 . . . and the sleeve portion 18," the means 54 require the manual grasping and separating of "a pair of graspable wings 56 at the proximal end 38 of the sleeve." (Col. 8, ll. 27-33.) Applicant submits that the manual grasping and separation of the graspable wings 56 is not the same as "advancing the carrier assembly towards the distal end of the elongate member, the carrier assembly causing the skin to separate from the outer surface of the elongate member from a proximal end of the skin toward a distal end of the skin," as recited, in part, by independent claim 1, "advancing the carrier assembly towards the distal end of the elongate member, the advancement of the carrier assembly causing the sleeve member to be disrupted from the proximal end of the sleeve member toward the distal end of the sleeve member" as recited, in part, by independent claim 17, or "advancing the carrier assembly towards the distal end of the elongate member, the advancement of the carrier assembly causing the sleeve member to be expanded from the proximal end of the sleeve member toward the distal end of the sleeve member," as recited, in part, by independent claim 20.

Furthermore, the Office Action has not cited, nor has Applicant found, any portion of *Martinez* or *Kanner* that remedies the deficiencies of *Green* and *Fontaine*. Therefore, because *Green*, *Fontaine*, *Martinez*, and *Kanner*, whether individually or in combination, fail to teach

each and every element of independent claims 1, 17, and 20, as presently amended, Applicant respectfully requests that the § 103 rejections be withdrawn. Applicant also respectfully submits that the pending dependent claims are allowable for at least the same reasons set forth above.

C. CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 18th day of September, 2009.

Respectfully submitted,

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